

Proceedings from a Multitumor CME Symposium Focused on Key Clinical Presentations and Papers in Oncology

CME INFORMATION

TARGET AUDIENCE

This activity is intended for medical oncologists, hematologists, hematology-oncology fellows and other allied cancer professionals.

OVERVIEW OF ACTIVITY

Clinical controversies and uncertainties persist in the management of all common cancers, and thousands of ongoing research trials worldwide attempt to provide new answers to long-standing clinical questions. As these trials reach maturity, clinical investigators initially present new data in abridged format at large scientific conferences and subsequently in full data sets formally published as part of peer-reviewed journals. Today, numerous annual oncology conferences release new clinical data and hundreds of peer-reviewed publications feature articles related to cancer research, treatment and practical management. The extensive list of available treatment options poses a challenge to the practicing clinician who must maintain knowledge of appropriate clinical management strategies across a vast spectrum of liquid and solid tumors.

These proceedings from a daylong symposium combine the perspectives of 16 renowned investigators with a review of key recent presentations and publications across breast cancer, gastrointestinal cancers, genitourinary cancers, multiple myeloma, non-small cell lung cancer and Hodgkin and non-Hodgkin lymphoma, including chronic lymphocytic leukemia, to assist medical oncologists and hematologists in the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Effectively apply the results of practice-changing clinical research to the care of patients with breast, lung, gastrointestinal, genitourinary and select hematologic cancers.
- Compare and contrast the clinical relevance of recent pivotal cancer research results published in peer-reviewed journals and/or presented at major oncology conferences.
- Recall ongoing trials in breast, lung, gastrointestinal, genitourinary and select hematologic cancers, and refer appropriate patients for study participation.

- Use an understanding of tumor biomarkers and single and multigene signatures to individualize the care of patients with cancer.
- Educate patients with diverse hematologic cancers and solid tumors about the benefits and risks of new therapeutic agents and strategies.
- Refine or validate existing cancer-specific treatment algorithms based on exposure to new data sets and the perspectives of tumor-specific clinical investigators.

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CONTENT VALIDATION AND DISCLOSURES

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Hardware/Software Requirements:

A high-speed Internet connection A monitor set to 1280 x 1024 pixels or more Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later

Adobe Flash Player 10.2 plug-in or later Adobe Acrobat Reader (Optional) Sound card and speakers for audio

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SELECT PUBLICATIONS

Multiple Myeloma

Boccadoro M et al. Melphalan/prednisone/lenalidomide (MPR) versus high-dose melphalan and autologous transplantation (MEL200) plus lenalidomide maintenance or no maintenance in newly diagnosed multiple myeloma (MM) patients. *Proc ASCO* 2013; Abstract 8509.

Gay F et al. Bortezomib induction, reduced-intensity transplantation, and lenalidomide consolidation-maintenance for myeloma: Updated results. *Blood* 2013;122(8):1376-83.

Goldschmidt H et al. Pomalidomide plus low-dose dexamethasone (POM + LoDEX) versus high-dose dexamethasone (HiDEX) in relapsed/refractory multiple myeloma (RRMM): Impact of cytogenetics in MM-003. *Proc ASCO* 2013; Abstract 8528.

Heintel D et al. High expression of cereblon (CRBN) is associated with improved clinical response in patients with multiple myeloma treated with lenalidomide and dexamethasone. *Br J Haematol* 2013;161(5):695-700.

Jakubowiak AJ et al. Treatment outcome with the combination of carfilzomib, lenalidomide, and low-dose dexamethasone (CRd) for newly diagnosed multiple myeloma (NDMM) after extended follow-up. *Proc ASCO* 2013; Abstract 8543.

Kumar S et al. Weekly MLN9708, an investigational oral proteasome inhibitor (PI), in relapsed/refractory multiple myeloma (MM): Results from a phase I study after full enrollment. *Proc ASCO* 2013; Abstract 8514.

Kumar SK et al. A phase 1/2 study of weekly MLN9708, an investigational oral proteasome inhibitor, in combination with lenalidomide and dexamethasone in patients with previously untreated multiple myeloma (MM). *Proc ASH* 2012; Abstract 332.

Lokhorst HM et al. Phase I/II dose-escalation study of daratumumab in patients with relapsed or refractory multiple myeloma. *Proc ASCO* 2013; Abstract 8512.

Lonial S et al. Phase (Ph) I/II study of elotuzumab (Elo) plus lenalidomide/dexamethasone (Len/dex) in relapsed/refractory multiple myeloma (RR MM): Updated Ph II results and Ph I/II long-term safety. *Proc ASCO* 2013; Abstract 8542.

Mateos MV et al. **Lenalidomide plus dexamethasone for high-risk smoldering multiple myeloma.** *N Engl J Med* 2013;369(5):438-47.

Mellqvist UH et al. Bortezomib consolidation after autologous stem cell transplantation in multiple myeloma: A Nordic Myeloma Study Group randomized phase 3 trial. *Blood* 2013;121(23):4647-54.

Palumbo A et al. Second primary malignancies (SPM) in newly diagnosed myeloma (MM) patients treated with lenalidomide (Len): Meta-analysis of 6,383 individual patient data (IPD). *Proc ASCO* 2013; Abstract 8517.

San Miguel JF et al. MM-003: A phase III, multicenter, randomized, open-label study of pomalidomide (POM) plus low-dose dexamethasone (LoDEX) versus high-dose dexamethasone (HiDEX) in relapsed/refractory multiple myeloma (RRMM). *Proc ASCO* 2013; Abstract 8510.

Weisel KC et al. Pomalidomide plus low-dose dexamethasone (POM + LoDEX) versus high-dose dexamethasone (HiDEX) in relapsed/refractory multiple myeloma (RRMM): MM-003 analysis of patients (pts) with moderate renal impairment (RI). *Proc ASCO* 2013; Abstract 8527.

Lymphomas

Brown JR et al. Final results of a phase 1 study of idelalisib (GS-1101), a selective inhibitor of phosphatidylinositol 3-kinase p110 delta (P13Kd), in patients with relapsed or refractory CLL. *Proc ASCO* 2013; Abstract 7003.

Chen RW et al. Brentuximab vedotin as first line salvage therapy in relapsed/refractory HL. Proc ASH 2012; Abstract 3699.

Davids MS et al. Updated results of a phase I first-in-human study of the BCL-2 inhibitor ABT-199 (GDC-0199) in patients with relapsed/refractory non-Hodgkin lymphoma (NHL). *Proc ASCO* 2013; Abstract 8520.

Delarue R et al. ROCHOP study: A phase III randomized study of CHOP compared to romidepsin-CHOP in untreated peripheral T-cell lymphoma. *Proc ASCO* 2013; Abstract TPS8616.

Dunleavy K et al. **Dose-adjusted EPOCH-rituximab therapy in primary mediastinal B-cell lymphoma.** *N Engl J Med* 2013;368(15):1408-16.

Duvic M et al. Results of a phase II trial of brentuximab vedotin (SGN-35) for CD30+ cutaneous T-cell lymphomas and lymphoproliferative disorders. *Proc ASH* 2012:Abstract 3688.

Fanale MA et al. Brentuximab vedotin administered concurrently with multi-agent chemotherapy as frontline treatment of ALCL and other CD30-positive mature T-cell and NK-cell lymphomas. *Proc ASH* 2012; Abstract 60.

Flinn I et al. Secondary efficacy subanalysis by histology from the phase III BRIGHT study: First-line bendamustine-rituximab (BR) compared with standard R-CHOP/R-CVP for patients with advanced indolent non-Hodgkin lymphoma (NHL) or mantle cell lymphoma (MCL). *Proc ASCO* 2013; Abstract 8537.

Friedberg JW. Phase II study of alisertib, a selective aurora A kinase inhibitor, in relapsed and refractory aggressive B- and T-cell non-Hodgkin lymphomas. *J Clin Oncol* 2013;[Epub ahead of print].

Goede V et al. Obinutuzumab (GA101) plus chlorambucil (Clb) or rituximab (R) plus Clb versus Clb alone in patients with chronic lymphocytic leukemia (CLL) and preexisting medical conditions (comorbidities): Final stage 1 results of the CLL11 (B021004) phase III trial. *Proc ASCO* 2013; Abstract 7004.

Goy A et al. Phase II multicenter study of single-agent lenalidomide in subjects with mantle cell lymphoma who relapsed or progressed after or were refractory to bortezomib: The MCL-001 "EMERGE" study. *Proc ASH* 2012; Abstract 905.

Horwitz S et al. Belinostat in relapsed or refractory peripheral T-cell lymphoma (R/R PTCL) subtype angioimmunoblastic T-cell lymphoma (AITL): Results from the pivotal BELIEF trial. *Proc ICML* 2013; Abstract 153.

Jaeger U et al. Rituximab maintenance treatment versus observation in patients with aggressive B-cell lymphoma: Results of the AGMT NHL13 trial. *Proc ICML* 2013; Abstract 119.

Krathen M et al. Brentuximab vedotin demonstrates significant clinical activity in relapsed or refractory mycosis fungoides with variable CD30 expression. *Proc ASH* 2012:**Abstract 797**.

Leonard J et al. Tolerability and activity of combinations of the PI3Kδ inhibitor idelalisib (GS-1101) with rituximab and/or bendamustine in patients with previously treated, indolent non-Hodgkin lymphoma (iNHL): Updated results from a phase I study. *Proc ASCO* 2013;Abstract 8500.

Martin P et al. CALGB 50803 (ALLIANCE): A phase 2 trial of lenalidomide plus rituximab in patients with previously untreated follicular lymphoma. *Proc ICML* 2013; Abstract 063.

Moskowitz AJ et al. PET-adapted sequential therapy with brentuximab vedotin and augmented-ICE induces FDG-PET normalization in 92% of patients with relapsed and refractory Hodgkin lymphoma. *Proc ICML* 2013; Abstract 141.

Nowakowski GS et al. Combination of lenalidomide with R-CHOP (R2CHOP) is well-tolerated and effective as initial therapy for aggressive B-cell lymphomas — A phase II study. *Proc ASH* 2012; Abstract 689.

O'Brien SM et al. A phase 2 study of the selective phosphatidylinositol 3-kinase delta (PI3Kδ) inhibitor idelalisib (GS-1101) in combination with rituximab in treatment-naive patients ≥65 years with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). *Proc ASCO* 2013;Abstract 7005.

O'Connor OA et al. Belinostat, a novel pan-histone deacetylase inhibitor (HDACi), in relapsed or refractory peripheral T-cell lymphoma (R/R PTCL): Results from the BELIEF trial. *Proc ASCO* 2013; Abstract 8507.

Pingali SR et al. Clinical or survival benefit to routine surveillance imaging for classical Hodgkin lymphoma patients in first complete remission. *Proc ASCO* 2013; Abstract 8505.

Radford J et al. Involved field radiotherapy versus no further treatment in patients with clinical stages IA and IIA Hodgkin lymphoma and a 'negative' PET scan after 3 cycles ABVD. Results of the UK NCRI RAPID trial. *Proc ASH* 2012; Abstract 547.

Rummel MJ et al. Bendamustine plus rituximab versus CHOP plus rituximab as first-line treatment for patients with indolent and mantle-cell lymphomas: An open-label, multicentre, randomised, phase 3 non-inferiority trial. *Lancet Oncol* 2013;381(9873):1203-10.

Seymour J et al. Updated results of a phase I first-in-human study of the BCL-2 inhibitor ABT-199 (GDC-0199) in patients with relapsed/refractory (R/R) chronic lymphocytic leukaemia (CLL). *Proc ICML* 2013; Abstract 057.

Study of pralatrexate versus observation following CHOP-based chemotherapy in previously undiagnosed peripheral T-cell lymphoma patients. NCT01420679

Study of the effectiveness & safety of lenalidomide versus chlorambucil as first line therapy for elderly patients with B-cell CLL (the ORIGIN trial). NCT00910910

Thompson CA et al. Utility of post-therapy surveillance scans in DLBCL. Proc ASCO 2013; Abstract 8504.

Wang ML et al. Targeting BTK with ibrutinib in relapsed or refractory mantle-cell lymphoma. *N Engl J Med* 2013;369(6):507-16.

Wiestner A et al. Single agent ibrutinib (PCI-32765) is highly effective in chronic lymphocytic leukemia (CLL) patients with 17p deletion. *Proc ICML* 2013; Abstract 008.

Wilson WH et al. The Bruton's tyrosine kinase (BTK) inhibitor, ibrutinib (PCI-32765), has preferential activity in the ABC subtype of relapsed/refractory de novo diffuse large B-cell lymphoma (DLBCL): Interim results of a multicenter, open-label, Phase 2 study. *Proc ASH* 2012; Abstract 686.

Non-Small Cell Lung Cancer

A randomized, multicenter, open-label phase 3 study of gemcitabine-cisplatin chemotherapy plus necitumumab (IMC-11F8) versus gemcitabine-cisplatin chemotherapy alone in the first-line treatment of patients with stage IV squamous non-small cell lung cancer (NSCLC). NCT00981058

Bradley JD et al. A randomized phase III comparison of standard-dose (60 Gy) versus high-dose (74 Gy) conformal chemoradiotherapy with or without cetuximab for stage III non-small cell lung cancer: Results on radiation dose in RTOG 0617. *Proc ASCO* 2013:Abstract 7501.

Halmos B et al. Erlotinib beyond progression study: Randomized phase II study comparing chemotherapy plus erlotinib with chemotherapy alone in EGFR tyrosine kinase inhibitor (TKI)-responsive, non-small cell lung cancer (NSCLC) that subsequently progresses. *Proc ASCO* 2013; Abstract 8114.

Lazzari C et al. Randomized proteomic stratified phase III study of second-line erlotinib (E) versus chemotherapy (CT) in patients with inoperable non-small cell lung cancer (PROSE). *Proc ASCO* 2013; Abstract LBA8005.

Planchard D et al. Interim results of phase II study BRF113928 of dabrafenib in BRAF V600E mutation-positive non-small cell lung cancer (NSCLC) patients. *Proc ASCO* 2013; Abstract 8009.

Reck M et al. Nintedanib (BIBF 1120) plus docetaxel in NSCLC patients progressing after first-line chemotherapy: LUME Lung 1, a randomized, double-blind phase III trial. *Proc ASCO* 2013; Abstract LBA8011.

Sequist LV et al. Phase III study of afatinib or cisplatin plus pemetrexed in patients with metastatic lung adenocarcinoma with EGFR mutations. *J Clin Oncol* 2013;31(27):3327-34.

Shaw AT et al. Clinical activity of the ALK inhibitor LDK378 in advanced, ALK-positive NSCLC. *Proc ASCO* 2013; Abstract 8010.

Socinski MA et al. A phase III study of pemetrexed (Pem) plus carboplatin (Cb) plus bevacizumab (Bev) followed by maintenance pem plus bev versus paclitaxel (Pac) plus Cb plus bev followed by maintenance bev in stage IIIb or IV nonsquamous non-small cell lung cancer (NS-NSCLC): Overall and age group results. *Proc ASCO* 2013; Abstract 8004.

Socinski MA et al. Safety and efficacy of weekly *nab*®-paclitaxel in combination with carboplatin as first-line therapy in elderly patients with advanced non-small-cell lung cancer. *Ann Oncol* 2013;24(2):314-21.

Soria JC et al. Results of the prospective, randomized, and customized NSCLC adjuvant phase II trial (IFCT-0801, TASTE trial) from the French Collaborative Intergroup. *Proc ASCO* 2013; Abstract 7505.

Spigel DR et al. Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). *Proc ASCO* 2013; Abstract 8008.

Wu YL et al. LUX-Lung 6: A randomized, open-label, phase III study of afatinib (A) versus gemcitabine/cisplatin (GC) as first-line treatment for Asian patients (pts) with EGFR mutation-positive (EGFR M+) advanced adenocarcinoma of the lung. *Proc ASCO* 2013; Abstract 8016.

Zinner R et al. Randomized, open-label, phase III study of pemetrexed plus carboplatin (PemC) followed by maintenance pemetrexed versus paclitaxel/carboplatin/bevacizumab (PCB) followed by maintenance bevacizumab in patients with advanced nonsquamous (NS) non-small cell lung cancer (NSCLC). *Proc ASCO* 2013; Abstract LBA8003.

Gastrointestinal Cancers

A randomized, multicenter, adaptive phase II/III study to evaluate the efficacy and safety of trastuzumab emtansine (T-DM1) versus taxane (docetaxel or paclitaxel) in patients with previously treated locally advanced or metastatic Her2-positive gastric cancer, including adenocarcinoma of the gastroesophageal junction. NCT01641939

Arnold R et al. Placebo controlled, double blind, prospective, randomized study on the effect of octreotide LAR in the control of tumor growth in patients with metastatic neuroendocrine midgut tumors (PROMID): Results on long-term survival. *Proc ASCO* 2013:Abstract 4030.

Assenat E et al. Sorafenib (S) alone versus S combined with gemcitabine and oxaliplatin (GEMOX) in first-line treatment of advanced hepatocellular carcinoma (HCC): Final analysis of the randomized phase II GONEXT trial (UNICANCER/FFCD PRODIGE 10 trial). *Proc ASCO* 2013; Abstract 4028.

Bajetta E et al. Everolimus in combination with octreotide LAR as the first-line treatment for advanced neuroendocrine tumors: A phase II trial of the ITMO (Italian Trials in Medical Oncology) group. *Proc ASCO* 2013; Abstract 4136.

Bang YJ et al. A randomized, open-label, phase III study of lapatinib in combination with weekly paclitaxel versus weekly paclitaxel alone in the second-line treatment of HER2 amplified advanced gastric cancer (AGC) in Asian population: Tytan study. Gastrointestinal Cancers Symposium 2013; Abstract 11.

Bechter OE et al. Open-label, phase IIIb, multicenter, expanded access study of everolimus in patients with advanced neuroen-docrine tumors (NET). *Proc ASCO* 2013; Abstract 4138.

Bennouna J et al. Continuation of bevacizumab after first progression in metastatic colorectal cancer (ML18147): A randomised phase 3 trial. *Lancet Oncol* 2013;14(1):29-37.

Casali PG et al. Imatinib failure-free survival (IFS) in patients with localized gastrointestinal stromal tumors (GIST) treated with adjuvant imatinib (IM): The EORTC/AGITG/FSG/GEIS/ISG randomized controlled phase III trial. *Proc ASCO* 2013;Abstract 10500.

Cheng A-L et al. Regorafenib (REG) in patients with hepatocellular carcinoma (HCC) progressing following sorafenib: An ongoing randomized, double-blind, phase III trial. *Proc ASCO* 2013; Abstract TPS4163.

Cook N et al. Cougar-02: A randomized phase III study of docetaxel versus active symptom control in patients with relapsed esophago-gastric adenocarcinoma. *Proc ASCO* 2013; Abstract 4023.

Corcoran RB et al. Pharmacodynamic and efficacy analysis of the BRAF inhibitor dabrafenib (GSK436) in combination with the MEK inhibitor trametinib (GSK212) in patients with BRAFV600 mutant colorectal cancer (CRC). *Proc ASCO* 2013; Abstract 3507.

Cunningham D et al. Bevacizumab plus capecitabine versus capecitabine alone in elderly patients with previously untreated metastatic colorectal cancer (AVEX): An open-label, randomized phase 3 trial. *Lancet Oncol* 2013;14(11):1077-85.

Demetri GD et al. Efficacy and safety of regorafenib for advanced gastrointestinal stromal tumours after failure of imatinib and sunitinib (GRID): An international, multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol* 2013;381(9863):295-302.

Demetri GD et al. Mutational analysis of plasma DNA from patients (pts) in the phase III GRID study of regorafenib (REG) versus placebo (PL) in tyrosine kinase inhibitor (TKI)-refractory GIST: Correlating genotype with clinical outcomes. *Proc ASCO* 2013; Abstract 10503.

Douillard JY et al. Panitumumab-FOLFOX4 treatment and RAS mutations in colorectal cancer. *N Engl J Med* 2013;369(11):1023-34.

Falcone A et al. FOLFOXIRI/bevacizumab (bev) versus FOLFIRI/bev as first-line treatment in unresectable metastatic colorectal cancer (mCRC) patients (pts): Results of the phase III TRIBE trial by GONO group. *Proc ASCO* 2013; Abstract 3505.

Fuchs CS et al. REGARD: A phase III, randomized, double-blind trial of ramucirumab and best supportive care (BSC) versus placebo and BSC in the treatment of metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma following disease progression on first-line platinum- and/or fluoropyrimidine-containing combination therapy. Gastrointestinal Cancers Symposium 2013;Abstract LBA5.

Grothey A et al. Time profile of adverse events (AEs) from regorafenib (REG) treatment for metastatic colorectal cancer (mCRC) in the phase III CORRECT study. *Proc ASCO* 2013; Abstract 3637.

Hecht JR et al. Lapatinib in combination with capecitabine plus oxaliplatin (CapeOx) in HER2-positive advanced or metastatic gastric, esophageal, or gastroesophageal adenocarcinoma (AC): The TRIO-013/LOGiC trial. *Proc ASCO* 2013; Abstract LBA4001.

Heinemann V et al. Analysis of KRAS/NRAS and BRAF mutations in FIRE-3: A randomized phase III study of FOLFIRI plus cetuximab or bevacizumab as first-line treatment for wild-type (WT) KRAS (exon 2) metastatic colorectal cancer (mCRC) patients. ECCO-ESMO 2013; Abstract LBA17.

Heinemann V et al. Randomized comparison of FOLFIRI plus cetuximab versus FOLFIRI plus bevacizumab as first-line treatment of KRAS wild-type metastatic colorectal cancer: German AIO study KRK-0306 (FIRE-3). *Proc ASCO* 2013;Abstract LBA3506.

Hobday TJ et al. Multicenter phase II trial of temsirolimus (TEM) and bevacizumab (BEV) in pancreatic neuroendocrine tumor (PNET). *Proc ASCO* 2013; Abstract 4032.

Kerr DJ, Shi Y. Biological markers: Tailoring treatment and trials to prognosis. Nat Rev Clin Oncol 2013;10(8):429-30.

Koeberle D et al. Bevacizumab continuation versus no continuation after first-line chemo-bevacizumab therapy in patients with metastatic colorectal cancer: A randomized phase III noninferiority trial (SAKK 41/06). *Proc ASCO* 2013; Abstract 3503.

Koopman M et al. Maintenance treatment with capecitabine and bevacizumab versus observation after induction treatment with chemotherapy and bevacizumab in metastatic colorectal cancer (mCRC): The phase III CAIRO3 study of the Dutch Colorectal Cancer Group (DCCG). *Proc ASCO* 2013; Abstract 3502.

Loprinzi CL et al. Phase III randomized, placebo (PL)-controlled, double-blind study of intravenous calcium/magnesium (CaMg) to prevent oxaliplatin-induced sensory neurotoxicity (sNT), NO8CB: An Alliance for Clinical Trials in Oncology study. *Proc ASCO* 2013; Abstract 3501.

Love N et al. Is adjuvant oxaliplatin overutilized in colon cancer? 408 cases from the practices of 102 oncologists. Gastrointestinal Cancers Symposium 2013; Abstract 479.

MacKenzie S et al. A pilot phase II multicenter study of nab-paclitaxel (Nab-P) and gemcitabine (G) as preoperative therapy for potentially resectable pancreatic cancer (PC). *Proc ASCO* 2013; Abstract 4038.

Mitchel EP et al. North American (NA) subgroup results from VELOUR: Ziv-aflibercept versus placebo (pbo) plus FOLFIRI in mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen. Gastrointestinal Cancers Symposium 2013; Abstract 465.

Peng ZW et al. Radiofrequency ablation with or without transcatheter arterial chemoembolization in the treatment of hepatocellular carcinoma: A prospective randomized trial. *J Clin Oncol* 2013;31(4):426-32.

Primrose JN et al. A randomized clinical trial of chemotherapy compared to chemotherapy in combination with cetuximab in KRAS wild-type patients with operable metastases from colorectal cancer: The new EPOC study. *Proc ASCO* 2013; Abstract 3504.

RAINBOW: A randomized, multicenter, double-blind, placebo-controlled phase 3 study of weekly paclitaxel with or without ramucirumab (IMC-1121B) drug product in patients with metastatic gastric adenocarcinoma, refractory to or progressive after first-line therapy with platinum and fluoropyrimidine. NCT01170663

Randomized, placebo-controlled, double-blind phase 2 study of mFOLFOX6 chemotherapy plus ramucirumab drug product (IMC-1121B) versus mFOLFOX6 plus placebo for advanced adenocarcinoma of the esophagus, gastroesophageal junction or stomach. NCT01246960

REACH: A multicenter, randomized, double-blind, phase 3 study of ramucirumab (IMC-1121B) drug product and best supportive care (BSC) versus placebo and BSC as second-line treatment in patients with hepatocellular carcinoma following first-line therapy with sorafenib. NCT01140347

RECAP: A randomized phase 2 study of ruxolitinib efficacy and safety in combination with capecitabine for subjects with recurrent or treatment refractory metastatic pancreatic cancer. NCT01423604

REFRAME: A phase II study of single-agent regorafenib in the first line treatment of frail and/or unfit for polychemotherapy patients with metastatic colorectal cancer (mCRC). NCT01875380

Schultheis B et al. Regorafenib in combination with FOLFOX or FOLFIRI as first- or second-line treatment of colorectal cancer: Results of a multicenter, phase Ib study. *Ann Oncol* 2013;24(6):1560-7.

Tabernero J et al. Pertuzumab (P) with trastuzumab (T) and chemotherapy (CTX) in patients (pts) with HER2-positive metastatic gastric or gastroesophageal junction (GEJ) cancer: An international phase III study (JACOB). *Proc ASCO* 2013; Abstract TPS4150.

Tan J et al. The outcome of patients with advanced hepatocellular carcinoma (HCC) in pre- and post-sorafenib eras using the SEER database. Gastrointestinal Cancers Symposium 2013; Abstract 276.

Van Cutsem E et al. Regorafenib (REG) in progressive metastatic colorectal cancer (mCRC): Analysis of age subgroups in the phase III CORRECT trial. *Proc ASCO* 2013; Abstract 3636.

Von Hoff DD et al. Results of a randomized phase III trial (MPACT) of weekly nab-paclitaxel plus gemcitabine versus gemcitabine alone for patients with metastatic adenocarcinoma of the pancreas with PET and CA19-9 correlates. *Proc ASCO* 2013; Abstract 4005.

Breast Cancer

Campone M et al. Effect of visceral metastases on the efficacy and safety of everolimus in postmenopausal women with advanced breast cancer: Subgroup analysis from the BOLERO-2 study. *Eur J Cancer* 2013;49(12):2621-32.

Datko FM et al. Phase II study of pertuzumab, trastuzumab, and weekly paclitaxel in patients with HER2-overexpressing metastatic breast cancer (MBC). *Proc ASCO* 2013; Abstract 606.

Davies C et al. Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years after diagnosis of oestrogen receptor-positive breast cancer: ATLAS, a randomised trial. *Lancet Oncol* 2013;381(9869):805-16.

Gill CE et al. Efficacy and safety of first-line (1L) pertuzumab (P), trastuzumab (T), and docetaxel (D) in HER2-positive MBC (CLEOPATRA) in patients previously exposed to trastuzumab. *Proc ASCO* 2013; Abstract 600.

Goldhirsch A et al. Personalizing the treatment of women with early breast cancer: Highlights of the St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2013. *Ann Oncol* 2013;24(9):2206-23.

Hornberger J et al. Clinical validity/utility, change in practice patterns, and economic implications of risk stratifiers to predict outcomes for early-stage breast cancer: A systematic review. J Natl Cancer Inst 2012;104(14):1068-79.

Hurvitz SA et al. Phase II randomized study of trastuzumab emtansine versus trastuzumab plus docetaxel in patients with human epidermal growth factor receptor 2-positive metastatic breast cancer. *J Clin Oncol* 2013;31(9):1157-63.

lwamoto M et al. Phase II study of eribulin mesylate as first- or second-line therapy for metastatic HER2-negative breast cancer. *Proc ASCO* 2013; Abstract TPS1140.

Jerusalem G et al. Evaluation of everolimus (EVE) in HER2+ advanced breast cancer (BC) with activated PI3K/mTOR pathway: Exploratory biomarker observations from the BOLERO-3 trial. ECCO-ESMO 2013; Abstract 16.

Johnston SR et al. Fulvestrant plus anastrozole or placebo versus exemestane alone after progression on non-steroidal aromatase inhibitors in postmenopausal patients with hormone-receptor-positive locally advanced or metastatic breast cancer (SoFEA): A composite, multicentre, phase 3 randomised trial. *Lancet Oncol* 2013;14(10):989-98.

Kaufman PA et al. A phase III, open-label, randomized study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer (MBC) previously treated with anthracyclines and taxanes: Subgroup analyses. *Proc ASCO* 2013; Abstract 1049.

O'Regan R et al. Phase III, randomized, double-blind, placebo-controlled multicenter trial of daily everolimus plus weekly trastuzumab and vinorelbine in trastuzumab-resistant, advanced breast cancer (BOLERO-3). *Proc ASCO* 2013; Abstract 505.

Richard G et al. aTTom: Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years in 6,953 women with early breast cancer. *Proc ASCO* 2013;Abstract 5.

Rugo HS et al. Correlation of molecular alterations with efficacy of everolimus in hormone-receptor-positive, HER2-negative advanced breast cancer: Results from BOLERO-2. Breast Cancer Symposium 2013; Abstract 142.

Wildiers H et al. T-DM1 for HER2-positive metastatic breast cancer (MBC): Primary results from TH3RESA, a phase 3 study of T-DM1 vs treatment of physician's choice. ECCO-ESMO 2013; Abstract 15.

Prostate Cancer and Renal Cell Carcinoma

A safety and efficacy study of oral MDV3100 in chemotherapy-naive patients with progressive metastatic prostate cancer (PREVAIL). NCT01212991

Cho DC et al. Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with metastatic renal cell carcinoma (mRCC). *Proc ASCO* 2013; Abstract 4505.

Crawford ED et al. The utility of prostate-specific antigen in the management of advanced prostate cancer. BJU Int 2013;112(5):548-60.

Drake CG et al. Survival, safety, and response duration results of nivolumab (anti-PD-1; BMS-936558; ONO-4538) in a phase I trial in patients with previously treated metastatic renal cell carcinoma: Long-term patient follow-up. *Proc ASCO* 2013; Abstract 4514.

Efstathiou E et al. The effects of enzalutamide (ENZA) in combination with abiraterone acetate (AA) in patients with bone metastatic castration resistant prostate cancer (mCRPC). ECCO-ESMO 2013; Abstract 2854.

Hussain M et al. Intermittent versus continuous androgen deprivation in prostate cancer. N Engl J Med 2013;368(14):1314-25.

Motzer RJ et al. A phase III comparative study of nivolumab (anti-PD-1; BMS-936558; ONO-4538) versus everolimus in patients (pts) with advanced or metastatic renal cell carcinoma (mRCC) previously treated with antiangiogenic therapy. *Proc ASCO* 2013; Abstract TPS4592.

Motzer RJ et al. Pazopanib versus sunitinib in metastatic renal-cell carcinoma. N Engl J Med 2013;369(8):722-31.

Motzer RJ et al. Record-3: Phase II randomized trial comparing sequential first-line everolimus (EVE) and second-line sunitinib (SUN) versus first-line SUN and second-line EVE in patients with metastatic renal cell carcinoma (mRCC). *Proc ASCO* 2013; Abstract 4504.

Parker C et al. Alpha emitter radium-223 and survival in metastatic prostate cancer. N Engl J Med 2013;369(3):213-23.

Porta C et al. Efficacy and safety of everolimus in elderly patients with metastatic renal cell carcinoma: An exploratory analysis of the outcomes of elderly patients in the RECORD-1 trial. *Eur Urol* 2012;61(4):826-33.

Rathkopf DE et al. Phase I study of ARN-509, a novel antiandrogen, in the treatment of castration-resistant prostate cancer. J Clin Oncol 2013;31(28):3525-30.

Ryan CJ et al. Abiraterone in metastatic prostate cancer without previous chemotherapy. N Engl J Med 2013;368(2):138-48.

Schellhammer PF et al. Lower baseline prostate-specific antigen is associated with a greater overall survival benefit from sipuleucel-T in the Immunotherapy for Prostate Adenocarcinoma Treatment (IMPACT) trial. *Urology* 2013;81(6):1297-302.

Scher HI et al. Impact of on-study corticosteroid use on efficacy and safety in the phase III AFFIRM study of enzalutamide (ENZA), an androgen receptor inhibitor. Genitourinary Cancers Symposium 2013; Abstract 6.

Smith DC et al. Cabozantinib in patients with advanced prostate cancer: Results of a phase II randomized discontinuation trial. *J Clin Oncol* 2013;31(4):412-9.

Smith MR et al. Efficacy and safety of enzalutamide (ENZA) monotherapy in hormone-naive prostate cancer (HNPC). *Proc ASCO* 2013; Abstract 5001.

Van den Eertwegh AJ et al. Safety of everolimus by treatment duration in patients with advanced renal cell cancer in an expanded access program. *Urology* 2013;81(1):143-9.

Vogelzang NJ et al. Efficacy and safety of radium-223 dichloride (Ra-223) in castration-resistant prostate cancer (CRPC) patients with bone metastases who did or did not receive prior docetaxel (D) in the phase III ALSYMPCA trial. *Proc ASCO* 2013; Abstract 5068.

Vogelzang NJ et al. Updated analysis of radium-223 dichloride (Ra-223) impact on skeletal-related events (SRE) in patients with castration-resistant prostate cancer (CRPC) and bone metastases from the phase III randomized trial (ALSYMPCA). Genitourinary Cancers Symposium 2013; Abstract 11.